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(54) Title: **SAFETY DEVICE FOR A SYRINGE**

(57) Abstract: A syringe safety device comprises telescoping inner and outer members. The members include complementary projections and recesses to limit the full extension of the inner member and to lock the inner member in place once it has been fully extended. The inner member includes a ring at the distal end which extends radially outward of the outer member and is pushed against to deploy the inner member. The outer member is secured to the proximal flange of a syringe received within the safety device. A clip or cover is attached to the outer member and secures the outer member to the syringe flange.

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## SAFETY DEVICE FOR A SYRINGE

Background of the Invention

The present invention relates to the shielding of a syringe needle to protect against contact with the syringe needle after use.

Syringes are commonly used to administer medications and other fluids into a patient, or to aspirate or withdraw a fluid from a patient. Syringes may be marketed in a prefilled condition, wherein a set dosage of medicament is already contained therein, typically in a form ready for use or requiring reconstitution. Alternatively, syringes may be provided empty for aspiration purposes or to be filled from a vial or other source of medicament for injection purposes.

When a syringe is used, contact of the syringe needle with a patient can lead to contamination of the syringe, including the needle, with various contagious micro-organisms. The contaminated syringe and needle then pose a risk to anyone handling or near the syringe, if the person accidentally pricks or contacts himself or another person with the contaminated needle.

The potential for a needle stick is increased under circumstances where use and disposal of the needle may be less than optimal. For example, schizophrenia patients are sometimes brought into an emergency room in an agitated state and may need to be physically restrained. In order to calm the patient as quickly as possible, healthcare professionals administer injections of appropriate medications. Under these circumstances there can be an increased risk that the needle will be inadvertently contacted by the person administering the injection or by others in the vicinity.

There is a need to provide a syringe which includes a guard for the syringe needle after use, thereby protecting the users and others from possible contact with the exposed

needle tip. The protective system must be simple to use and reliable in operation, must not be susceptible to premature deployment, and must not interfere with the normal use of the syringe.

### Brief Summary of the Invention

The present invention generally provides a safety device for a syringe having a needle for injection into a patient. The safety device includes an outer member and an inner member sized to receive the syringe. The outer member is secured to the syringe. The inner member is telescopically received within the outer member and movable between a first, retracted position in which the needle is exposed for use, and a second, extended position in which the needle is covered after use. The outer member and inner member are configured to limit the extension of the inner member with respect to the outer member and to lock the inner member in the extended position.

In one embodiment, the outer member of the safety device includes a cylindrical body and a shoulder against which a flange of the syringe is received. A separate clip or connector may be used to further secure the syringe to the safety device. In an alternate embodiment, the outer member includes a backstop within which a flange of the syringe is received and retained by securement of a cover thereto.

In another embodiment, one of the inner and outer members includes a projection having a locking surface that fits within a recess on the other of the inner and outer members. The projection fits within the recess of the inner member to lock the inner member when it is in its extended position.

It is an object of the present invention to provide a safety device for a syringe which is easily fabricated, assembled and used, and which does not interfere with or limit normal operations of the syringe. The device is easily handled during use, and provides protection for the syringe body in the event of impact with the device.

A further object of the present invention is to provide a safety device which is readily coupled with a syringe, and which becomes integral with the syringe once assembled.

Another object of the present invention is to provide a safety device which permits adequate visibility of the syringe and its contents.

It is a further object of the present invention to provide a safety device which is readily extended to the protective position, particularly in the process of removing the syringe needle from a patient.

A further object of the present invention is to provide a safety device which is securely locked in the extended, safety position, and which fully covers the syringe needle in the extended position.

Further objects and advantages of the present invention will be apparent from the descriptions which follow.

### Brief Description of the Drawings

Figure 1 is a cross-sectional, perspective view of a first embodiment of a safety device combined with a syringe in accordance with the present invention, with the safety device shown in the initial, collapsed position.

Figure 2 is a cross-sectional view of the device of Figure 1 shown in the extended position.

Figure 3 is an elevational, perspective view of the syringe and safety device of Figure 1.

Figure 4 is a side, elevational view of the safety device according to the first embodiment of the invention.

Figure 5 is a side, cross-sectional view of the safety device of Figure 4.

Figure 6 is a side, cross-sectional view of the safety device of Figure 4 shown in the extended position.

Figure 7 is a side, cross-sectional view of the safety device viewed in the direction of the line 7-7 in Figure 4.

Figure 8 is a side, cross-sectional view of the safety device as shown in Figure 7 but in the extended position.

Figure 9 is a perspective view of a clip useful in securing a syringe to the safety device of Figure 1.

Figure 10 is a bottom, plan view of the clip of Figure 9.

Figure 11 is a partial, side view of the syringe and safety device coupled together by the clip of Figure 9.



Figure 12 is a side, cross-sectional view of the syringe and safety device assembly of Figure 11.

Figure 13 is a perspective view of an alternate embodiment of an outer member useful in accordance with the present invention.

Figure 14 is a side, cross-sectional view of the outer member of Figure 13.

Figure 15 is a perspective view of an alternate embodiment of an inner member useful in combination with the outer member of Figure 13.

Figure 16 is a side, cross-sectional view of the inner member of Figure 15.

Figure 17 is a side, cross-sectional view of the alternate embodiment of the safety device with the syringe coupled thereto with a clip, and with the inner member shown in the fully extended position relative to the outer member.

Figure 18 is a perspective view of a second alternate embodiment of an inner member useful in the present invention.

Figure 19 is a side, cross-sectional view of the inner member of Figure 18 assembled with a complementary outer member.

Figure 20 is a side, elevational view of another embodiment of an inner member useful in accordance with the present invention, and particularly including centering arms.

Figure 21 is a side, cross-sectional view of the inner member taken in the direction of line 21-21 in Figure 20.

Figure 22 is a perspective view of another embodiment of an outer member useful with the present invention in combination with the inner member shown in Figure 20.

Figure 23 is a side, elevational view of the outer member taken in the direction of line 23-23 in Figure 22.

Figure 24 is a side, cross-sectional view of the outer member of Figure 23.

Figure 25 is a side, elevational view of the outer member taken in the direction of line 25-25 in Figure 23.

Figure 26 is a side, cross-sectional view of the outer member as shown in Figure 25.

Figure 27 is a plan view of the proximal end of the outer member of Figure 22.

Figure 28 is a top perspective view of a backstop cover useful with the outer member of Figure 22 to secure a syringe to the safety device.

Figure 29 is a bottom, perspective view of the backstop cover of Figure 28.

Figure 30 is a side, cross-sectional view of the backstop cover.

Figure 31 is a bottom, plan view of the backstop cover.

Figure 32 is a perspective view of an assembled safety device in accordance with one embodiment of the present invention, and particularly showing a syringe secured therewith by the backstop and cover.

Figure 33 is a side, cross-sectional view of the assembled safety device and syringe of Figure 32.

### Detailed Description of the Invention

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to preferred embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications of the invention, and such further applications of the principles of the invention as illustrated herein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention satisfies the continuing need for protection of users and others against accidental needle sticks from a syringe. The safety device is attached to a syringe and becomes integral therewith to assure the presence of the safety device for use when required. The safety device is readily adapted for use with a variety of syringe types, including various types and sizes of needles. The safety device includes many advantages as detailed hereafter with respect to the drawings and description of the preferred embodiments.

Referring to Figs. 1-3, there is shown a combination syringe and safety device 10 in accordance with one embodiment of the present invention. The syringe 11 is received within the telescoping safety device 12 and is attached thereto by a clip shown in subsequent drawings. The safety device comprises an outer member 13 and a telescoping inner member 14. The safety device is extendable from a retracted position shown in Figure 1 to an extended position shown in Figure 2. In the retracted position, the full length of the needle is exposed for use.

The safety device includes means for limiting the distal extension of inner member 14 relative to outer member 13. The outer member includes a pair of longitudinal channels 15 located on opposite sides of the interior surface. The inner member includes a pair of opposed tabs 16 sized and positioned to be received within the channels 15. The distal end of each channel defines a shoulder 17. Each of the tabs 16 includes a distal surface 18 shaped to engage the respective shoulder 17. These abutting surfaces are shown as being generally perpendicular to the axis of the safety device, but other configurations providing a sufficient stop for distal travel of the inner member would be equally useful. Therefore, as shown in Figure 2, the distal travel of inner member 14 relative to outer member 13 is limited to the position when the surfaces 18 abut the shoulders 17.

The use of opposed tabs 16 received within channels 15 provides an exemplary means for controlling extension of the inner member, but various alternate approaches may be employed. For example, these members may be reversed such that the tabs are located on the outer member and the channels are located on the inner member. The number of such mechanisms is also not critical, as one or more such systems could be employed. The use of two opposed and identical mechanisms provides advantages such as symmetry to facilitate assembly, enhanced locking strength due to the duplication of the abutting surfaces, and greater stability for the safety device as the inner member is extended. Other approaches to controlling the extension of one member relative another are also known in the art and are contemplated herein.

The safety device further includes means for locking the inner member in the extended position once it has been fully deployed. As shown in Figures 1 and 2, the

inner member 14 includes at least one locking tab 19 which is initially received within an aperture 20 in the outer member. The tab 19 includes an angled distal surface 21 which is positioned adjacent a complementary, angled surface 22 of the outer member. The presence of these adjacent, angled surfaces enables the inner member 14 to be telescoped distally relative to the outer member as the tab 19 is forced inwardly along the angled surface 22. Sufficient clearance is provided between the interior of the inner member 14 and the exterior of the syringe 11 to permit the inner member to flex as the tab 19 is moved inwardly.

The requirement for the inner member to flex in this manner provides a resistance against the extension of the inner member relative the outer member, and initially retains the inner member in the retracted position. Accordingly, the amount of resistance can be predetermined by selection of the size of the tab 19, the angle and/or shape of the surfaces 21 and 22, the type and thickness of the materials, and other design parameters. This permits the safety device to be designed with a desired amount of effort being required to extend the inner member, thereby preventing premature deployment.

The proximal side of the tab 19 includes a locking surface 23 which engages a complementary shoulder 24 defined on the proximal side of a channel 25 defined by the outer member 15. Once the inner member has been fully extended and the tab 19 is positioned at the channel 25, the inwardly flexed inner member will force the tab 19 outwardly into the channel 25. The inner member is prevented from thereafter retracting into the outer member by the engagement of the locking surface 23 with the shoulder 24. As shown in Figure 2, the members are configured to provide a fairly close tolerance between the position at which further extension is prevented by tab 16 and at which

retraction is prevented by tab 19. This is shown by the slight gap 26 present in Figure 2 between tab 19 and shoulder 24. This provides a margin of room to assure that outward extension of the inner member will not be stopped before engagement of the locking feature for the extended position.

Variations in the design of the locking mechanism are also contemplated by the present invention. For example, the tab and receiving channel may be reversed such that the tab is carried by the outer member and the receiving channel is defined by the inner member. Also, the safety device preferably includes a pair of locking tabs and complementary channels positioned on opposite sides, thereby providing such advantages as symmetry for purposes of assembly, increased locking due to the presence of two systems, and greater stability for the safety device as the inner member is deployed. Other approaches to locking the extension of one member relative to another are also known in the art and are contemplated herein.

It will be noted that no guiding slot or channel is provided for the tab 19 as it slides along the interior of the outer member. Such a guide could be provided if desired. However, the orientation of the inner member relative to the outer member is assured by the sliding of the tabs 16 within the respective channels 15.

Assembly of the safety device is straightforward. For example, in this embodiment the inner member may be rotated from its assembled position relative to the outer member to avoid engagement between the tabs 19 and shoulders 24. In this position, the inner member is slid into the outer member to a point at least beyond the position at which the tabs 19 could be received within the channels 25. The inner member is then rotated relative to the outer member to move the tabs 16 into the

respective channels 15. Full insertion of the inner member into the outer member will cause the tabs 19 to be received within the apertures 20, thereby completing assembly of the safety device. It will be noted that the tabs 16 are provided with angled, proximal surfaces 27 which facilitate insertion of the inner member into the outer member.

Similarly, the distal end 28 of the outer member 13 may be provided with an inwardly tapered edge 29 which cooperates with the angled surface 27 to facilitate assembly of the two members.

The syringe 11 is secured to the outer member 13 in any manner suitable to assure proper operation of the safety device. For example, the syringe could be glued or otherwise directly connected with the outer member. Alternatively, coupling means may be employed to hold the syringe and the safety device together without such direct connection.

In one embodiment, the syringe is coupled with the safety device by a clip 30. The clip 30 provides for securement of the syringe to the safety device, and also provides other advantages, as hereafter described.

Clip 30 includes a proximal member 31 and a distal member 32 connected by a wall 33. The distal member 32 defines a central aperture 34 sized to receive the outer member 13, and an angled lead opening 35 to permit passage of the outer member therethrough into the central aperture. The lead opening reduces to a distance slightly less than the outside diameter of the outer member 13. Therefore, when the clip 30 is pushed over the outer member, it flexes outwardly in order for the outer member to be moved into the central aperture 34, thereby providing a means of attachment of the clip to the outer member.

The proximal member 31 similarly includes a central aperture 36 and a lead opening 37. The syringe 11 includes a plunger 38 which is received through the lead opening and into the central aperture 36 when the clip is attached to the safety device. The central aperture is sized to be sufficiently large to receive the plunger 38, but may also be sized sufficiently small as to prevent withdrawal of the stopper 39 received within the body 40 of the syringe. The clip 30 thereby makes the syringe safer to use in that the stopper 39 is not removable and the contents of the syringe therefore cannot be exposed.

The clip provides securement of the syringe with the safety device in the following manner. As shown particularly in Figure 12, the outer member 13 includes a radially-extending flange 41 and an axially-extending flange 42. The distal member 32 of the clip is received underneath the flange 41, and the proximal member 31 of the clip is received over the flange 42. In addition, flange 42 is displaced outwardly of the main body of the outer member, thereby defining a central recess 43 and a surrounding circumferential shoulder 44. Syringe 11 includes a flange 45 which extends outwardly at the proximal end of the syringe. Flange 45 is received within recess 43 and overlaps with shoulder 44. The proximal member 31 of the clip therefore sandwiches the flange 45 against the shoulder 44, thereby providing securement of the syringe with the safety device.

Assembly of the syringe with the safety device is therefore readily accomplished. The syringe 11 is simply inserted into the safety device with the flange 45 resting against the shoulder 44. The clip 30 is slid over the outer member 13 with the syringe plunger being received within central aperture 36 and the flange 41 being received between the



proximal and distal members of the clip. The clip is thereby firmly attached to the safety device, and the syringe is held securely with the safety device.

Suitable variations in the design of the clip are contemplated herein. The basic function of the clip is to couple the syringe with the safety device in a secure manner, and alternative designs which accomplish this function are equally useful with the present invention.

Referring to Fig. 3, syringe needle 46 is shielded by a cover 47 in its assembled state prior to use. The safety device is sized such that the cover 47 can remain in place during assembly of the syringe with the safety device. The cover should remain in place as long as possible, but can be readily removed when required, without disassembly of the syringe from the safety device.

The syringe may be coupled with the safety device without limiting other operations that may be required for the syringe prior to use. For example, certain medications may be prefilled in the syringe as a dry powder, and will therefore need to be reconstituted prior to use. This operation can be accomplished with the syringe and safety device assembled together, without deployment of the safety device. One advantage of the inventive design is that the outer member 13 can be grasped during such operations, thereby protecting against undesired deployment of the inner member. For example, the outer member 13 may be readily held while the needle cover 47 is removed and the syringe plunger 38 is then pulled outwardly to draw diluent into the syringe in order to reconstitute a powder medication.

The assembled syringe and safety device provide a solution to the combined need for utility of the syringe and reliable operation of the safety device to shield the syringe

needle after use. Prior to administration of a medicament to a patient, the combined unit has the safety device in the retracted position as shown in Figure 3.

To use the syringe to administer a medicament to a patient, the needle 46 is exposed and is inserted into the patient in the required fashion, for example intramuscularly or subcutaneously. In doing this, the device may be held in any of a variety of fashions by grasping the outer member appropriately. Such techniques are well known in the art, and are equally useful with the present invention. With the needle properly in position in the patient, the plunger is manipulated to administer the medication through the needle in conventional manner.

In certain instances it is desirable to first aspirate an amount of fluid from the patient into the body of the syringe. This is done, for example, in order to assure that the needle is not positioned within a blood vessel, which would be revealed if blood is aspirated into the syringe body. To accommodate this procedure, the members of the safety device are preferably made to be sufficiently transparent or translucent to permit the fluid within the syringe body to be visualized. Similarly, it is desirable to permit the syringe or its contents to be viewed through the safety device to monitor the administration of the medication or to check labeling or other information present on the syringe body. The inner and outer members are therefore preferably made of materials suitable to permit adequate visualization of the syringe and its contents for these and other purposes.

Once the medication has been administered, the inner member is extended to shield the syringe needle. To facilitate this operation, the inner member 14 includes a ring-shaped flange 48 that extends radially and axially outward of the outer member 13.

With the needle extending within the patient, the user of the device simply presses against the flange 48 of the inner member 14 as the outer member 13 is withdrawn from the patient. This operation readily and automatically extends the inner member relative to the outer member, moving the safety device into the safety position shown in Figure 2. As previously described, the extension of the inner member is limited by the tabs 16, and retraction of the inner member is prevented by locking tabs 19. The inner member thereby extends axially to a position that fully covers the needle and protects the user and others from accidental contact with the tip of the needle.

Importantly, the amount of force required to extend the inner member in this fashion is predetermined. This can be accomplished, for example, by selectively configuring the tabs 19, and particularly the complementary surfaces 21 of tabs 19 and surfaces 22 of outer member 13. It will be apparent that other modifications could also be made to control the force required, both for this embodiment and in alternate embodiments described hereafter.

The predetermined force required for extension is preferably selected to match the amount of force which a health care professional could be expected to apply under the circumstances of use. For example, some studies suggest that a force of between about 0.5 and about 4.0 pounds, preferably about 1.0 pounds of force is suitable. However, the design of the present invention guards against premature deployment since the user has the full length of the outer member to hold while performing such operations as reconstituting a medicament or aspirating fluid into the syringe, without the risk of deploying the inner member.

The clip 30 may also function as a means for holding the syringe during use. The perimeter of the clip may be sized to provide for contact surfaces for the user of the syringe, typically by the fingers. The contact of the distal member 32 with the underside of the flange 41 provides a bearing surface to permit pressure to be applied against the clip during use.

Referring to Figures 13-17, an alternate embodiment is shown. The components of this design are similar to those for the previous embodiment, except that certain modifications have been made. In this embodiment, the outer member 49 defines longitudinal slots 50 that receive tabs 51 of inner member 52 to provide an end stop for outward extension of the inner member relative to the outer member. The surfaces of the tabs 51 are configured as in the previous embodiment to facilitate assembly of the two components and to assure a definitive end stop to extension of the safety device once assembled.

Inner member 52 further includes an integral pair of opposed arms 53 carrying projections 54. The outer member includes corresponding apertures 55 to receive the projections 54 in the retracted position. As shown in Figure 15, the arms 53 are preferably formed integrally with the cylindrical body of the inner member, and may be cantled outwardly to assure that the projections 54 seat firmly within the receiving apertures 55 in the outer member. The size and shape of the arms 53 and projections 54 are readily modified to provide the desired resistance to sliding movement of the inner member, thereby determining the force required to deploy the inner member to the safety position shown in Figure 17.

As shown in Figure 17, the syringe is again depicted as coupled with the safety device by means of a clip 57. This clip functions essentially the same as for the previous embodiment, with the following differences. In this embodiment, the outer member 49 includes only an axially-extending flange 58. The clip 57 is received over the flange 58 and sandwiches the flange 59 of syringe 60 against an annular shoulder 61 formed by the outer member. The clip further includes a partial, circular lip 62 that extends distally. The lip 62 is sized and positioned to bear against the interior of the syringe to firmly center and hold the syringe in place within the outer member 49.

A related embodiment is depicted in Figures 18 and 19. This embodiment is similar to the previous embodiments, except that the outer member 63 includes inwardly-extending end stops 64. These end stops are received within corresponding slots 65 defined by the inner member 66. This embodiment therefore exemplifies a reversal of parts with regard to the portions providing the end stop for extension of the inner member. Similarly, other variations, including reversals of parts, can be employed for other aspects of the safety device.

Another embodiment is shown in Figures 20-33. Referring in particular to Figures 20-21, there is shown an inner member 67 which includes additional features to assist in centering and stabilizing the syringe body within the member. The inner member 67 includes slightly modified arms 68 including outwardly-extending projections 69 operating in the same manner as previously described with respect to the embodiment of Figure 15. These arms terminate a short distance from the proximal end 70 of the inner member, thereby providing proximal gaps 71 adjacent to the arms. The proximal end of the inner member also defines a pair of opposed recesses 72 aligned with the end

stops 73. These proximal gaps 71 and recesses 72 cooperate with alignment features of the outer member, as hereafter described.

The inner member 67 also includes a pair of arms 74, preferably formed integrally with the cylindrical body 75 of the inner member. Each of the arms 74 carries a pair of inwardly-extending projections 76 (Figure 21). These projections 76 are urged by the angled arms 74 against the body of a syringe received within the inner member 67, thereby centering and stabilizing the distal portion of the syringe within the member 67.

As shown in Figures 22-27 the outer member 77 includes a cylindrical body 78 and a backstop portion 79. The body 78 defines a pair of longitudinal slots 80 which receive the end stops 73 of the inner member to limit the extension of the inner member as previously described. The outer member also defines a pair of interior recesses 81 providing shoulders 82 against which are received the projections 69 of arms 68 when the inner cylinder is extended, thereby locking the inner cylinder in the fully extended position once deployed. This alternate embodiment is further distinguished by the inclusion of the backstop portion 79 with the outer member 77, preferably as an integral part therewith. The backstop portion cooperates with a backstop cover, described hereafter, to provide secure coupling of the syringe with the safety device. This embodiment therefore demonstrates a variation of the previous embodiments in terms of the coupling of the syringe with the safety device, and it will be appreciated that other such variations may be employed.

The backstop portion 79 and the outer member 77 include several features to assist in the centering of the syringe within the proximal part of the safety device. The outer member includes a plurality of ribs 85 along the entry to the interior of the

cylindrical body 78 which extend within the gaps 71 and recesses 72 of the inner member when the safety device is in the collapsed position. These ribs are positioned to receive the syringe body and to center it therebetween. The backstop 79 similarly includes a plurality of ribs 86 which are positioned to receive the flange of the syringe therebetween.

The ribs 85 may be positioned anywhere around the periphery of the cylindrical body 78 to sufficiently support and align a syringe received therein. As shown in Figure 22, the outer member includes six such ribs. A rib is aligned with each of the slots 80. A pair of ribs is positioned adjacent the position for each of the arms 68 of the inner member. These pairs of ribs are spaced apart a sufficient distance to permit the arms 68 to extend therebetween when the safety device is in the fully collapsed position.

The backstop portion 79 is further provided to couple the syringe with the safety device by sandwiching the syringe flange axially therein. Backstop 79 includes a base 87 that is secured to the body 78 and extends outwardly therefrom, forming a surface 88 which can assist in the use of the syringe, particularly in moving the plunger down into the syringe, as previously described. An upstanding perimeter wall 89 defines a circumferential groove 90 used to attach a cover to the backstop. A tab 91 extends beyond the wall 89 to complement the backstop cover as described hereafter.

The backstop cover 92 is shown in detail in Figures 28-31. Cover 92 includes a top 93 and a perimeter wall 94 extending downwardly therefrom. The wall 94 includes an inwardly-facing bead 95 that is sized and positioned to be received within the groove 90 of the backstop when the cover is attached thereto. A pair of walls 96 also extend from the top 93 and engage the interior surfaces 97 of the upstanding wall 89 of the

backstop to further secure the cover to the backstop. A pair of crush ribs 98 extend from the top 93 and are sized and positioned to deform against the proximal side of the syringe flange to securely hold the syringe within the safety device.

The cover 92 further defines a center hole 99 and a lead opening 100 extending thereto. The hole 99 is sized to receive the syringe plunger. The lead opening allows the cover to be moved over the plunger as the cover is attached to the backstop. Therefore, the cover can be attached to the backstop even when the plunger is already received within the syringe body placed within the safety device. The upstanding tab 91 is received within the lead opening 100 upon assembly of the cover to the backstop, thereby filling a portion of the opening 100.

This alternate embodiment of the present invention is assembled and used generally in the same fashion as described with respect to previous embodiments. The inner member 67 is inserted into the outer member 77 to the fully collapsed position. The arms 68 are aligned with the recesses 81 and pressed inwardly until the projections 69 have cleared past the shoulders 82. The inner member is then fully inserted into the outer member.

Once the inner and outer members have been assembled, a syringe 101 (Figure 33) is placed into the inner member and the flange 102 is received against the proximal edges of the ribs 85 and the proximal surface of the base 87. The distal portion of the syringe body 103 is centered in position by the arms 74 and projections 76 which bear against the body. The proximal portion of the syringe body is centered by the ribs 85 and 86.



The cover 92 is then attached to the backstop 79. Specifically, the backstop is moved over the plunger 104 by passing the plunger through the lead opening 100 and into the center hole 99. The cover is then moved axially onto the backstop and snapped into position as the bead 95 of the cover is received within the corresponding groove 90 of the backstop. The tab 91 is received within the lead opening to complete the perimeter surrounding the plunger. Also in this process, the crush ribs 98 are pressed against the syringe flange 102 and deform against the flange to securely hold the syringe in position.

Use of the assembled syringe and safety device is straightforward. The cap 105 is removed to expose the needle 106. The plunger 104 is manipulated as needed, for example, to reconstitute a dry medicament, to aspirate fluid into the syringe body, or to administer the medicament to a patient. The user is able to grasp the body of the outer member 77 and/or bear against the backstop 79 during these actions. Note that the center hole 99 is preferably sized to prevent the syringe stopper 107 from being pulled past the cover 92 during any of these processes, thus preserving sterility.

Once the medicament has been administered, the inner member 67 is deployed. The user simply presses against the ring 108 extending radially outwardly beyond the outer member at the same time that the outer member is pulled toward the user. This action preferably and easily occurs by the user pressing the ring 108 against the patient as the outer member is pulled away from the patient. In this manner, the needle 106 is drawn out of the patient and into the inner member 67. The device therefore provides the advantage that the needle is never exposed after it has been inserted into the patient. When the assembly is taken away from the patient, the inner member is already deployed into the fully-extended, safety position with the needle fully covered by the inner

member. Of course, the inner member can also be extended in the same fashion after the assembly is removed from the patient.

It is apparent that the described safety device of the present invention ensures that a syringe needle is protected against accidental contact with the user or others. The device uses an inner member which is manually extended to the safety position by telescoping outwardly with respect to an outer member held by the user of the device.

The components of the safety device may be fabricated from a variety of suitable materials. Sturdy plastic materials are preferred for their low cost and ease of fabrication. The materials should be sufficiently transparent or translucent, at least at relevant portions, to permit viewing of the syringe and its contents. This will enable the user to check the labeling of the syringe, and to confirm matters concerning materials drawn into or dispensed from the syringe body. The materials should also be selected to provide required strength and durability of the assembly in the collapsed and deployed conditions. For example, the components should be sufficiently strong as to endure the anticipated handling of the device during normal use, and foreseeable mishandling of the device such as by dropping.

The components have also been shown in particular shapes and configurations, but these are not required. For example, the inner and outer members have been shown as having cylindrical bodies because they are readily formed and assembled and are convenient for use. Other shapes for these components could also be used.

The safety device advantageously provides visual, audible and tactile feedback with regard to its assembly and use. The insertion of the inner member into the outer member provides a definite indication of the full insertion point as the projections 69 are

received within the recesses 109 (Figure 26) between the ribs 85. The cover 92 snaps onto the backstop 79 as an indication of its proper placement. The arms 68 and projections 69 drop into the recesses 81 as a similar confirmation that the inner member has been moved to and locked in the fully extended position.

The ring 108 is sized and positioned to minimize the possibility of accidental deployment of the inner member, while being easily used when appropriate. The ring may be colored or textured in a way to bring attention to it. This will help to alert the user to the fact that the ring is used for deployment of the inner member, and that it should be pushed against only when it is time to deploy the inner member.

The safety device is readily adapted to be used with a variety of syringes. The invention has been shown and described as used with a syringe having a fixed needle and standard needle cap. However, the safety device is designed to accommodate a variety of syringe and needle designs, including removable needles and needles of varying lengths. In one embodiment, the safety device is attached to a given syringe, and the entire assembly is discarded after use.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character.

What is claimed is:

1. A safety device for a syringe including a needle, which comprises:

an outer member;

an inner member sized to receive the syringe therein and telescopically received within said outer member, said inner member being extendible between a first, retracted position in which the needle is available for use, and a second, extended position in which the needle is covered;

limit means for limiting the extension of the inner member from the outer member;

lock means for locking the inner member in the extended position; and

means for securing said outer member to a syringe.

2. The device of claim 1 and which further includes means for presetting the amount of force required to move said inner member from the retracted position to the extended position.

3. The device of claim 1 in which said limit means comprises one of said inner and outer members defining a first abutting surface and the other of said inner and outer members defining a second abutting surface, the first abutting surface being spaced from the second abutting surface when said inner member is in the retracted position and being received against the second abutting surface when said inner member is in the extended position.

4. The device of claim 3 in which said inner member defines an outwardly extending tab and said outer member defines a longitudinal channel in which the tab is received, the tab including a distal abutting surface and the channel having a distal

abutting shoulder against which the distal surface is received when said inner member is in the extended position.

5. The device of claim 4 in which said inner member includes two tabs and said outer member defines two channels positioned on opposed sides of said inner and outer members, respectively.

6. The device of claim 5 in which the tab includes a sloped proximal surface.

7. The device of claim 1 in which said lock means comprises one of said inner and outer members defining a projection including a locking surface and the other of said inner and outer members including a distal recess defining a shoulder, the tab being received in the distal recess and the locking surface being positioned adjacent the shoulder when said inner member is in the extended position.

8. The device of claim 7 in which said inner member defines the projection and said outer member defines the distal recess in which the projection is received when said inner member is in the extended position.

9. The device of claim 8 in which said outer member includes a proximal recess in which the projection is received when said inner member is in the retracted position.

10. The device of claim 9 in which the projection includes a sloped distal surface and the proximal recess includes a sloped shoulder against which the distal surface of the projection is received as said inner member is moved from the retracted position to the extended position.

11. The device of claim 7 in which said inner member defines an arm which carries the projection, the arm being biased outwardly to move it into the recess of said outer member when said inner member is in the extended position.

12. The device of claim 11 in which said inner member includes two arms and corresponding projections and said outer member defines two recesses, the arms and recesses being positioned on opposed sides of said inner and outer members, respectively.

13. The device of claim 11 in which said outer member includes a distal opening adjacent the arm when said inner member is in the extended position.

14. The device of claim 1 in which said means for securing comprises means for securing to said outer member the syringe flange of a syringe received within said outer member.

15. The device of claim 14 in which said means for securing comprises said outer member defining a syringe shoulder against which the syringe flange is received, the syringe shoulder being received on the distal side of the syringe flange.

16. The device of claim 14 in which the syringe shoulder includes a plurality of centering elements positioned to bear against and center the syringe flange of a syringe received within said outer member.

17. The device of claim 15 in which said means for securing further comprises a connector secured to said outer member and including a portion positioned on the proximal side of the syringe flange to hold the syringe flange between said connector and the syringe shoulder.

18. The device of claim 17 in which the portion of said connector on the proximal side of the syringe flange includes means for preventing a syringe stopper from being removed from a syringe received within said inner member.

19. The device of claim 17 in which said connector is secured directly to the syringe shoulder of said outer member.

20. The device of claim 19 in which said connector is a clip including a first portion received adjacent the distal side of the syringe shoulder and a second portion received on the proximal side of the syringe shoulder and on the proximal side of the syringe flange of a syringe received within said outer member.

21. The device of claim 19 in which said connector is a cover which snap fits onto the proximal side of the syringe shoulder.

22. The device of claim 21 in which the cover includes a plurality of holding elements extending distally and positioned to bear against and stabilize a syringe received within said outer member.

23. The device of claim 22 in which the holding elements are crush ribs.

24. The device of claim 1 in which said outer member includes a plurality of inwardly extending centering ribs positioned to bear against and center the proximal portion of a syringe received within said outer member.

25. The device of claim 1 in which said inner member includes a plurality of inwardly extending centering arms positioned to bear against and center the distal portion of a syringe received within said inner member.

26. The device of claim 1 in which said inner member includes at its distal end a portion which extends radially-outward of said outer member and which is accessible for use in moving said inner member from the retracted position to the extended position.

27. A safety device for a syringe having a syringe flange and including a needle, which comprises:

an outer member;

an inner member sized to receive the syringe therein and telescopically received within said outer member, said inner member being extendible between a first, retracted position in which the needle is available for use, and a second, extended position in which the needle is covered;

one of said inner and outer members defining a first abutting surface and the other of said inner and outer members defining a second abutting surface, the first abutting surface being spaced from the second abutting surface when said inner member is in the retracted position and being received against the second abutting surface when said inner member is in the extended position;

one of said inner and outer members defining a projection including a locking surface and the other of said inner and outer members defining a distal recess defining a shoulder, the tab being spaced from the distal recess and the locking surface being spaced from the shoulder when said inner member is in the retracted position, the tab being received in the distal recess and the locking surface being positioned adjacent the shoulder when said inner member is in the extended position;

said outer member defining a syringe shoulder against which is received the syringe flange of a syringe received within said outer member, the syringe shoulder being positioned to be received on the distal side of the syringe flange; and

a connector secured to said outer member and including a portion positioned to be received on the proximal side of the syringe flange of a syringe received within said outer member and holding the syringe flange between said connector and the syringe shoulder.

28. The device of claim 27 in which said inner member defines an outwardly extending tab and said outer member defines a longitudinal channel in which the tab is



received, the tab including a distal abutting surface and the channel having a distal shoulder against which the distal surface is received when said inner member is in the extended position.

29. The device of claim 27 in which said inner member defines the projection and said outer member defines the distal recess in which the projection is received when said inner member is in the extended position.

30. The device of claim 29 in which said outer member includes a proximal recess in which the projection is received when said inner member is in the retracted position.

31. The device of claim 30 in which the projection includes a sloped distal surface and the proximal recess includes a sloped shoulder against which the distal surface of the projection is received as said inner member is moved from the retracted position to the extended position.

32. The device of claim 27 in which said connector is secured directly to the syringe shoulder of said outer member.

33. The device of claim 32 in which said connector is a clip including a first portion received adjacent the distal side of the syringe shoulder and a second portion received on the proximal side of the syringe shoulder and on the proximal side of the syringe flange of a syringe received within said outer member.

34. The device of claim 32 in which said connector is a cover which snap fits onto the proximal side of the syringe shoulder.

35. A safety syringe assembly which comprises:

a syringe including a body, a proximal flange, and a needle;

an outer member;

an inner member telescopically received within said outer member, said syringe being received within said inner member, said inner member being extendible between a first, retracted position in which the needle is exposed for use, and a second, extended position in which the needle is covered;

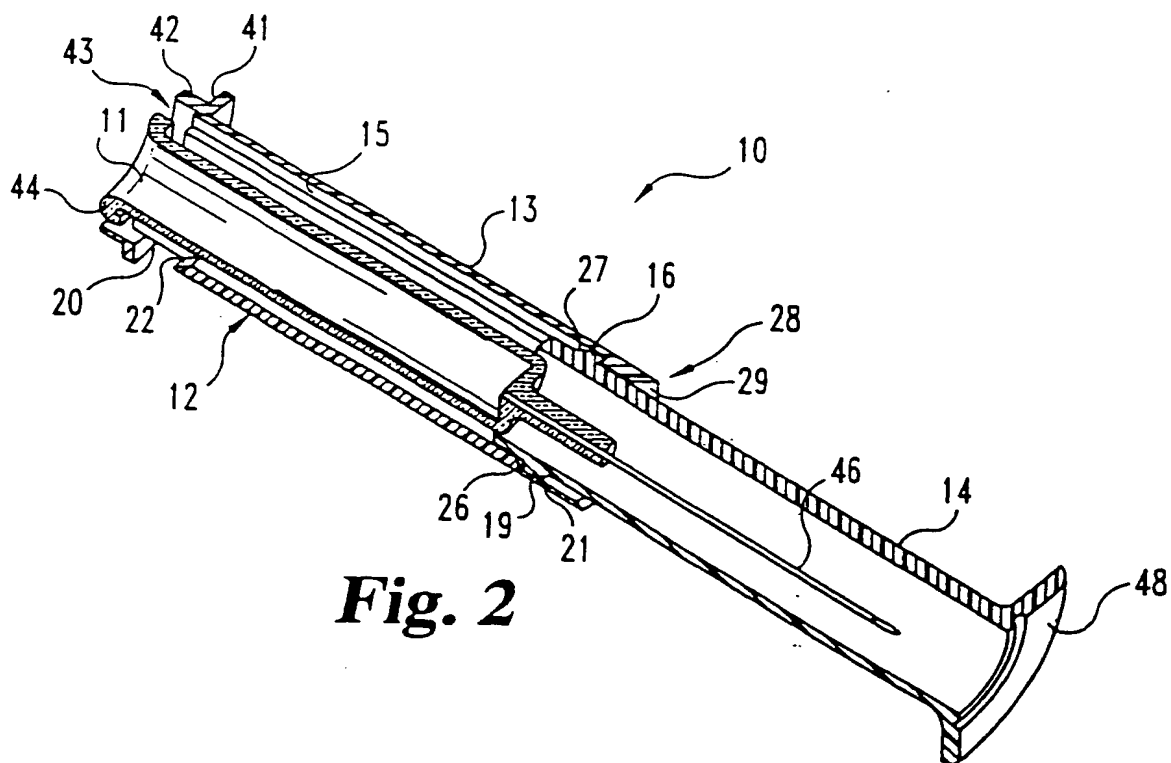
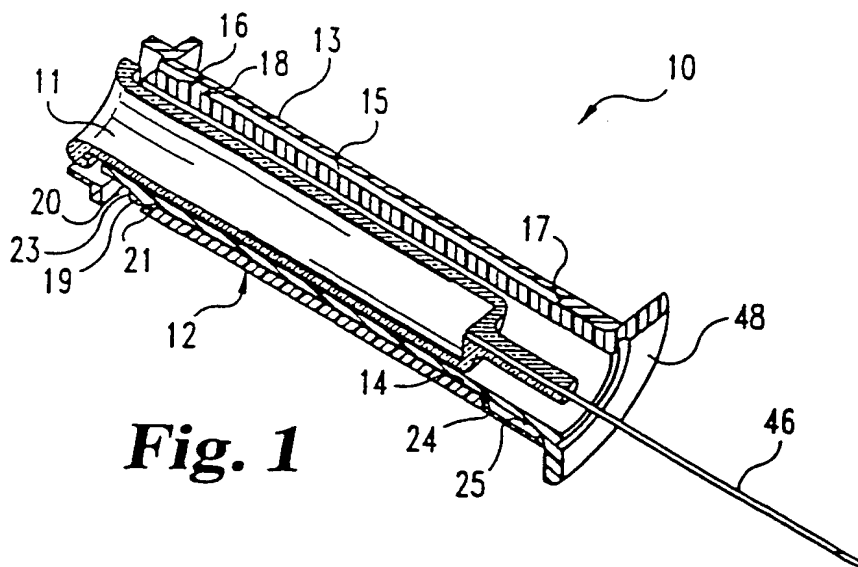
one of said inner and outer members defining a first abutting surface and the other of said inner and outer members defining a second abutting surface, the first abutting surface being spaced from the second abutting surface when said inner member is in the position and being received against the second abutting surface when said inner member is in the extended position;

one of said inner and outer members defining a projection including a locking surface and the other of said inner and outer members defining a distal recess defining a shoulder, the tab being spaced from the distal recess and the locking surface being spaced from the shoulder when said inner member is in the retracted position, the tab being received in the distal recess and the locking surface being positioned adjacent the shoulder when said inner member is in the extended position;

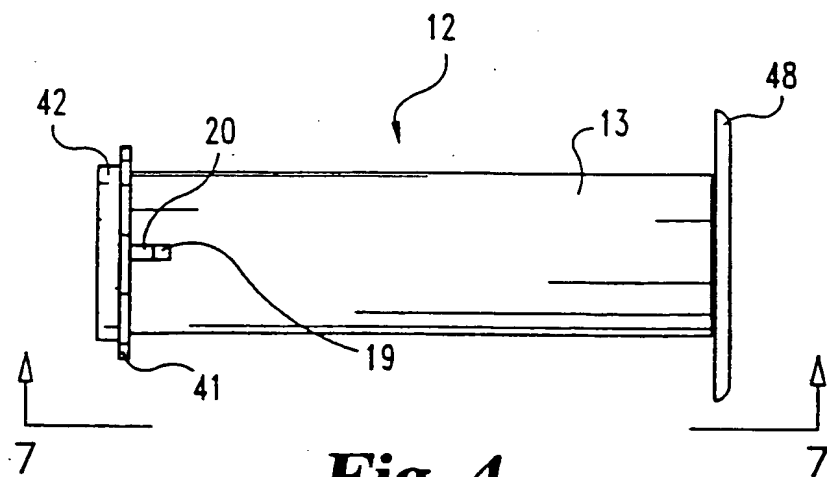
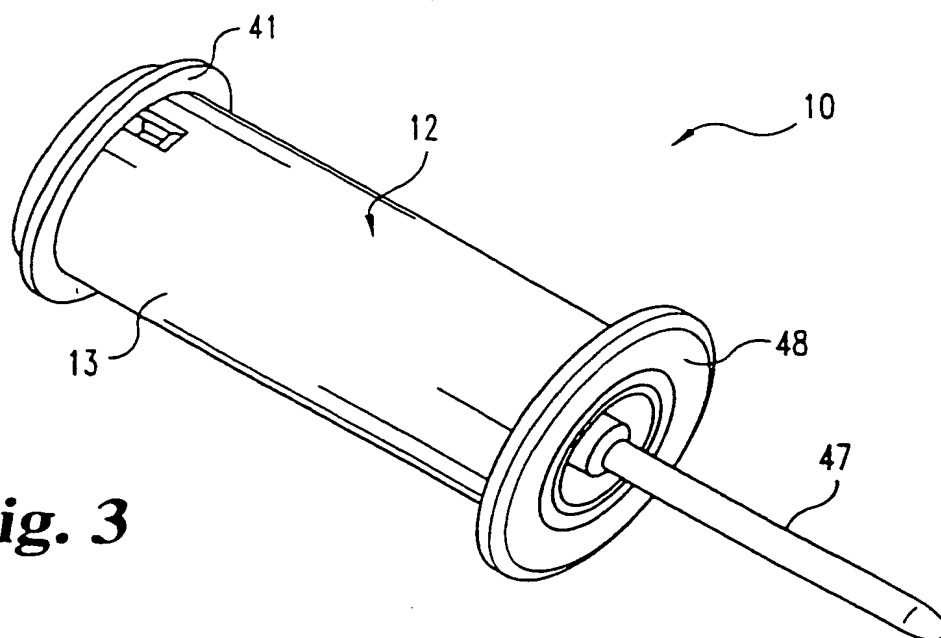
said outer member defining a syringe shoulder against which the syringe flange is received, the syringe shoulder being positioned on the distal side of the syringe flange of said syringe; and

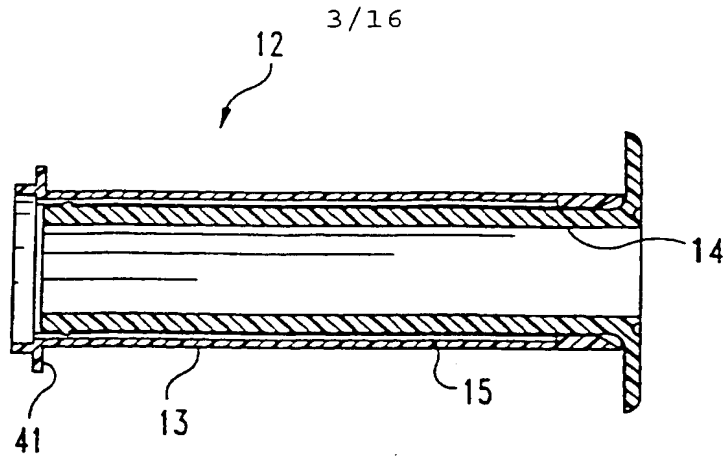
a connector secured to said outer member and including a portion positioned on the proximal side of the syringe flange and holding the syringe flange between said connector and the syringe shoulder.

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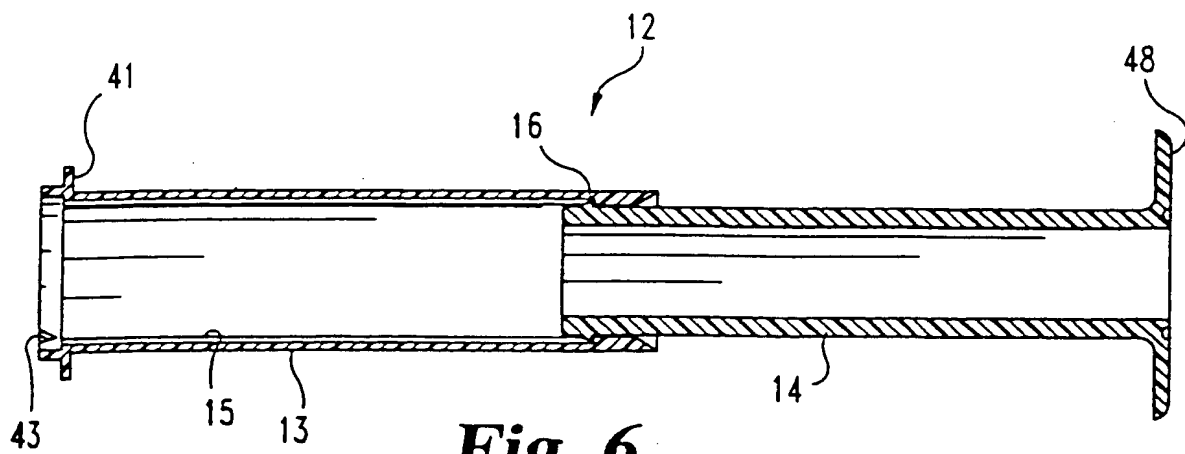


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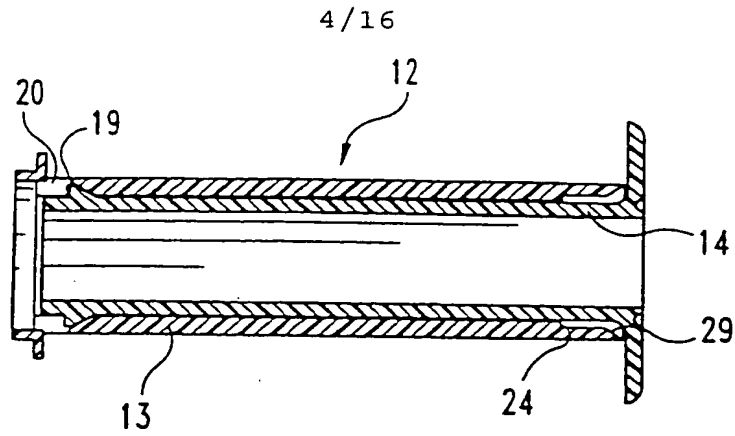
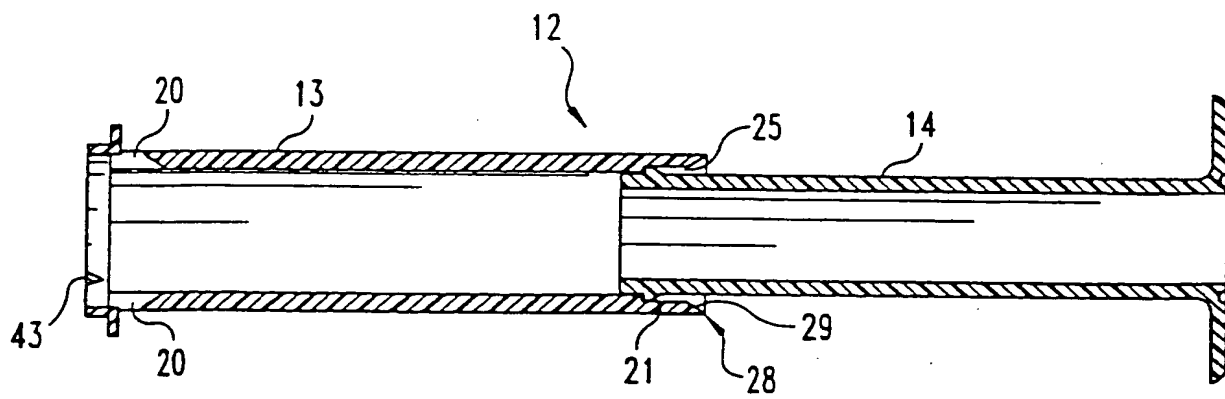
**Fig. 3****Fig 4**



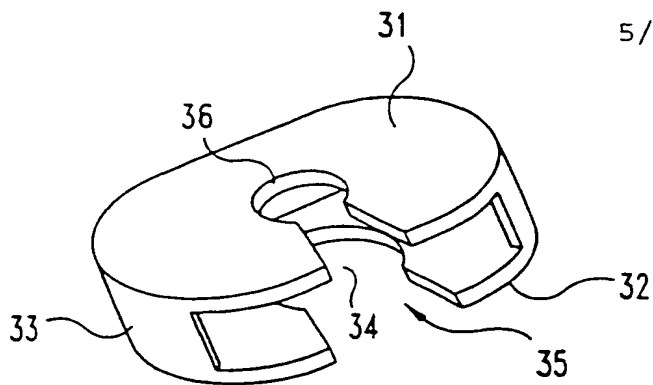
**Fig. 5**



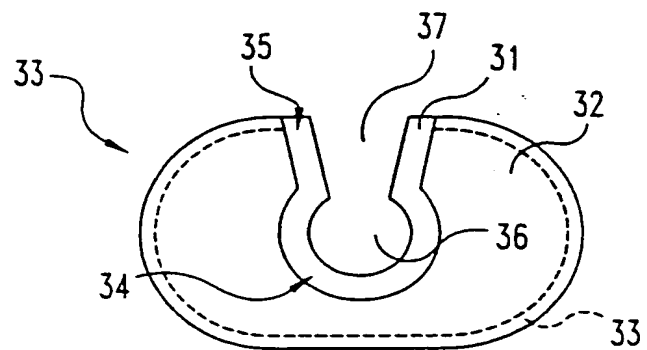
**Fig. 6**

**Fig. 7****Fig. 8**

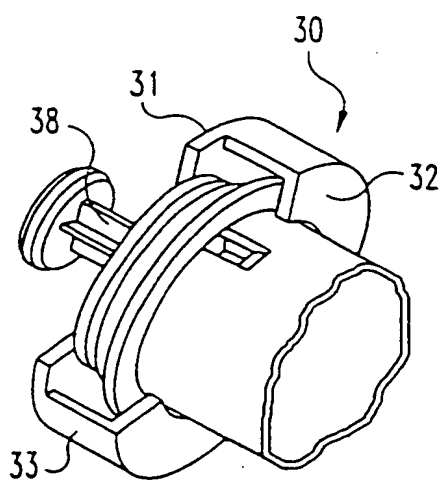
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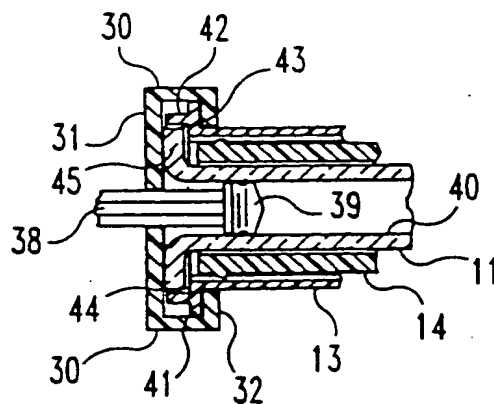
**Fig. 9**



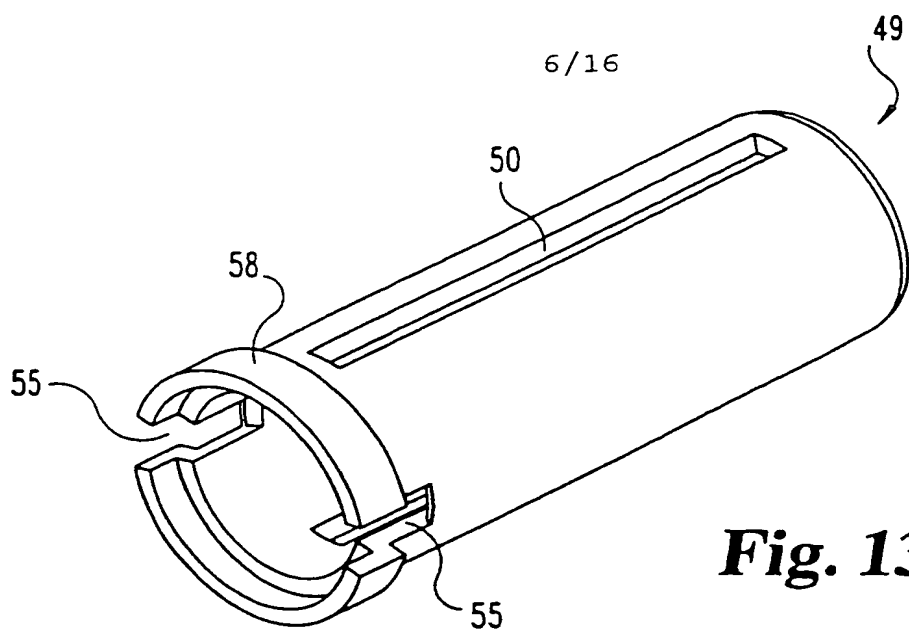
**Fig. 10**



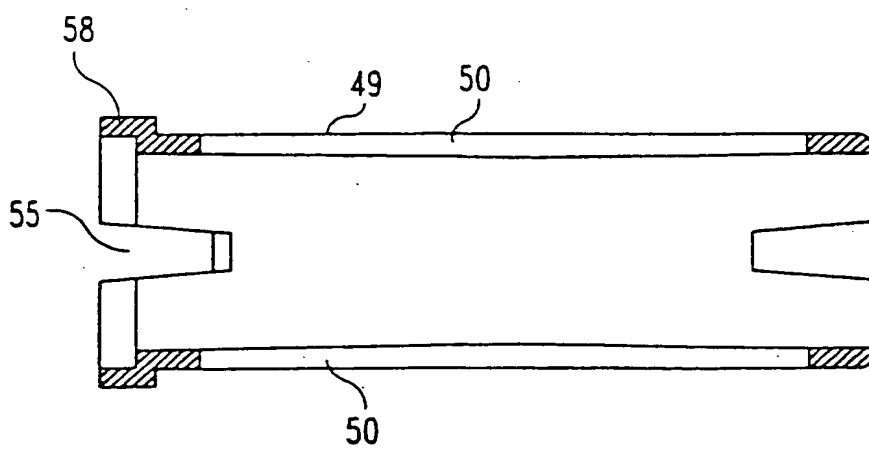
**Fig. 11**



**Fig. 12**



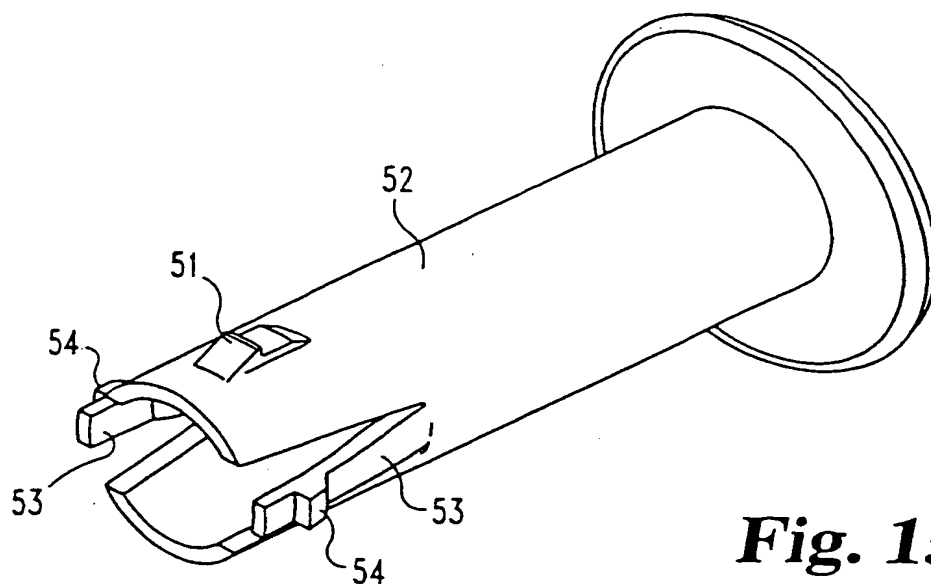
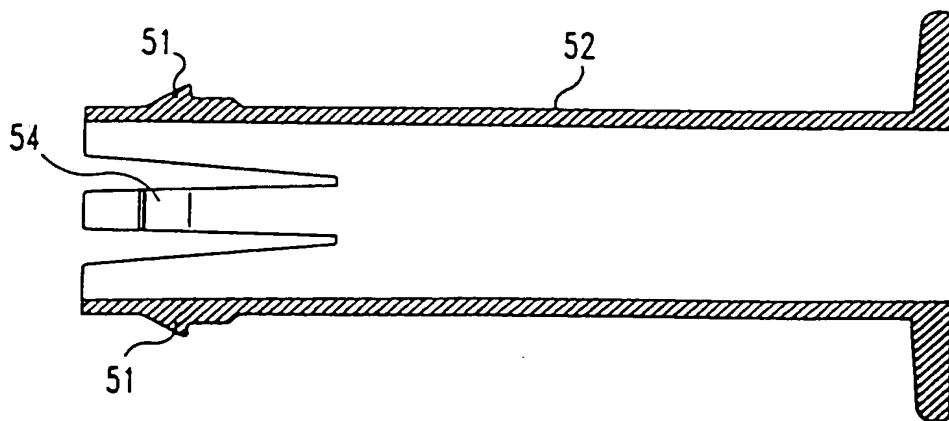
**Fig. 13**



**Fig. 14**



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**Fig. 15****Fig. 16**

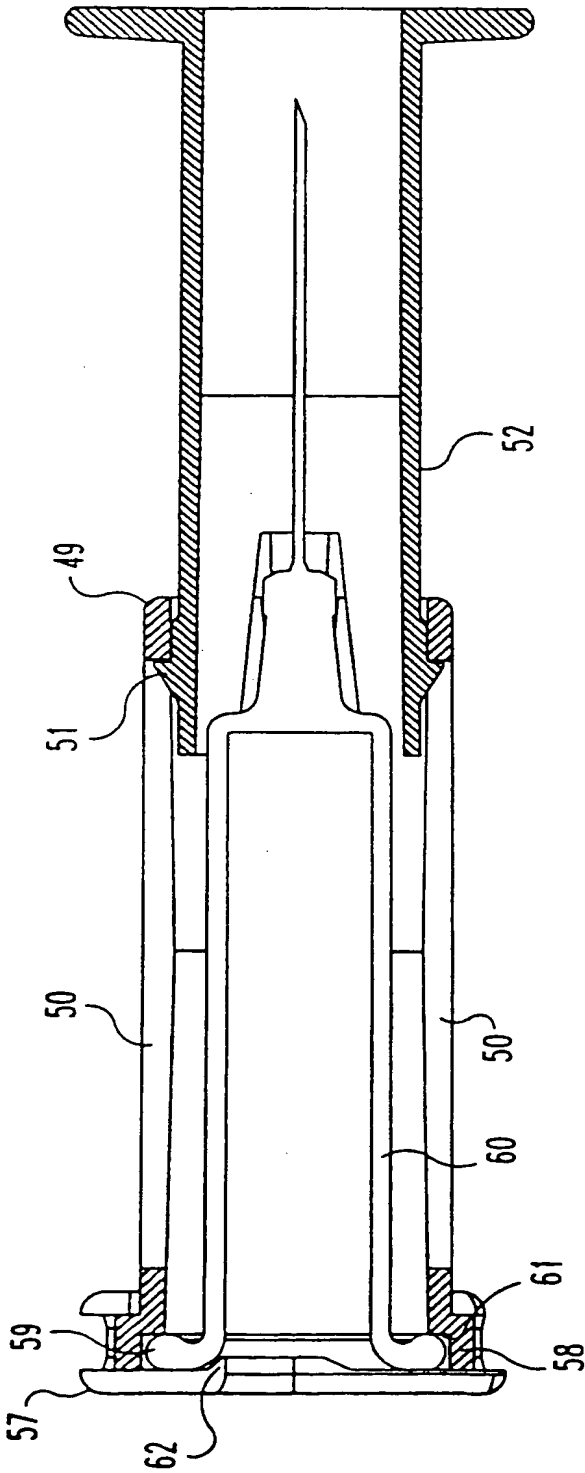
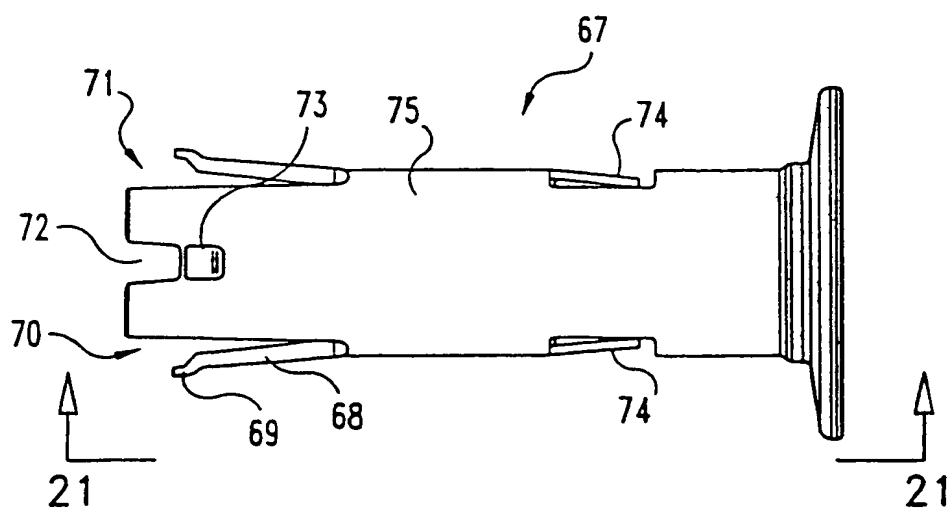
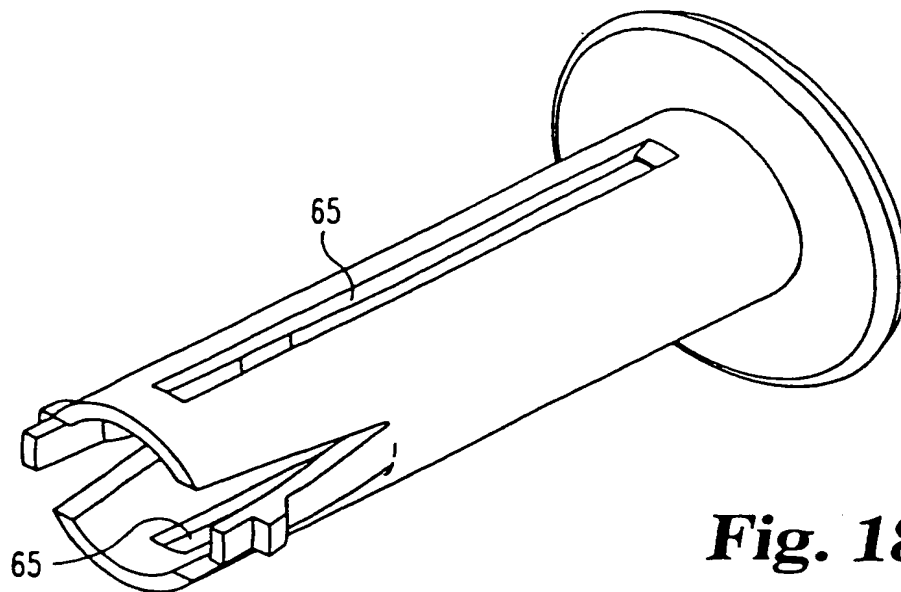


Fig. 17

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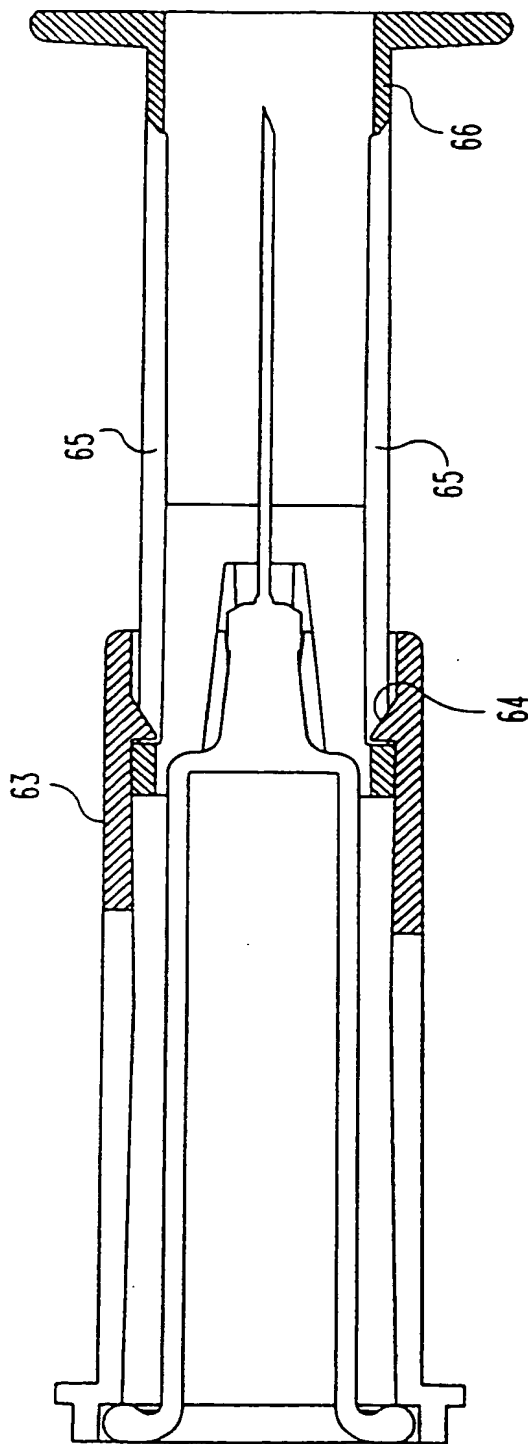
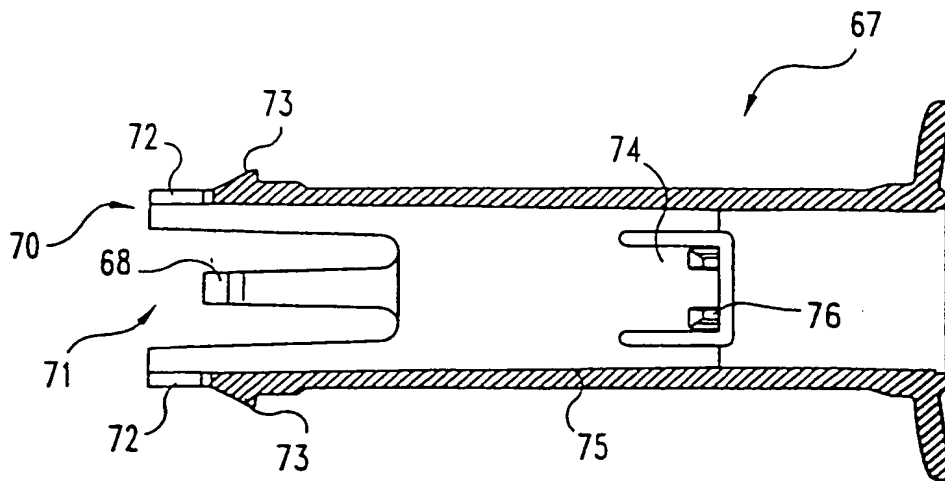
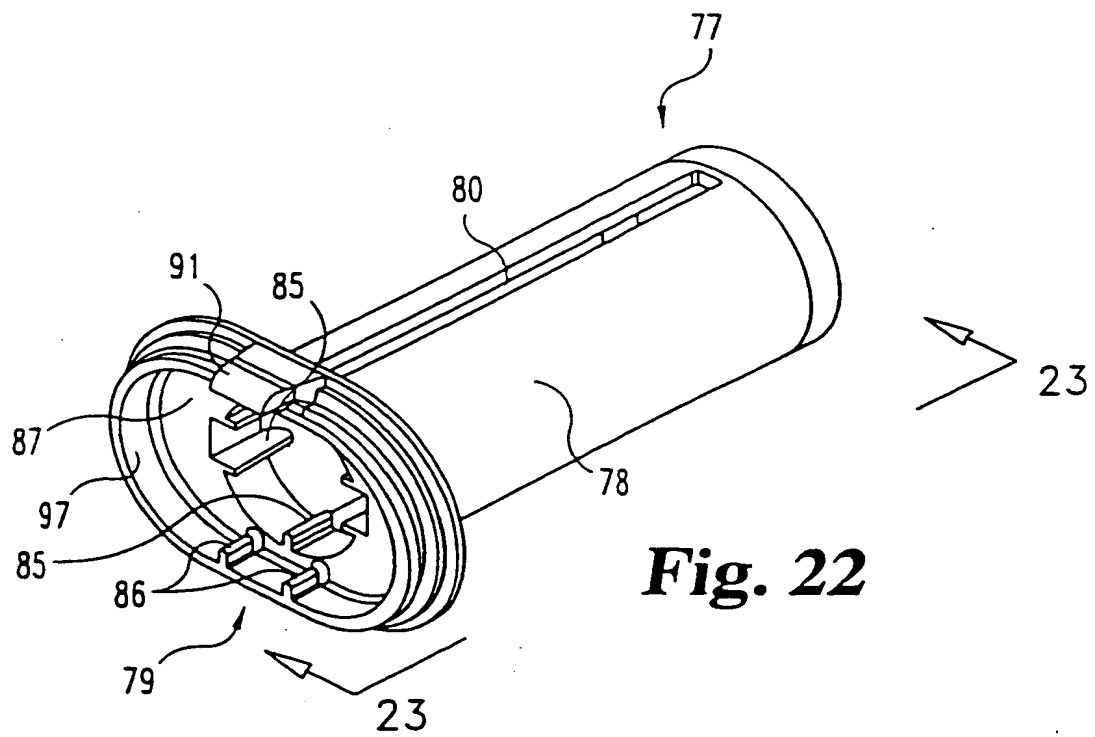


Fig. 19

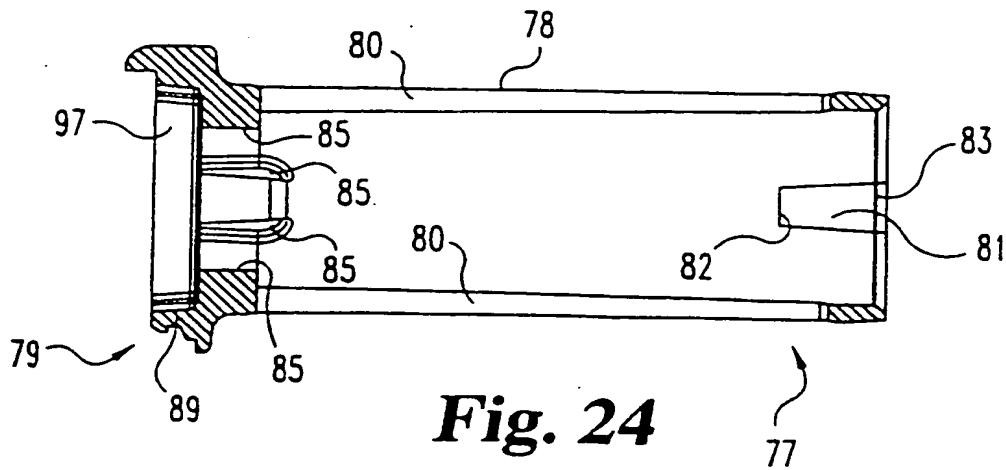
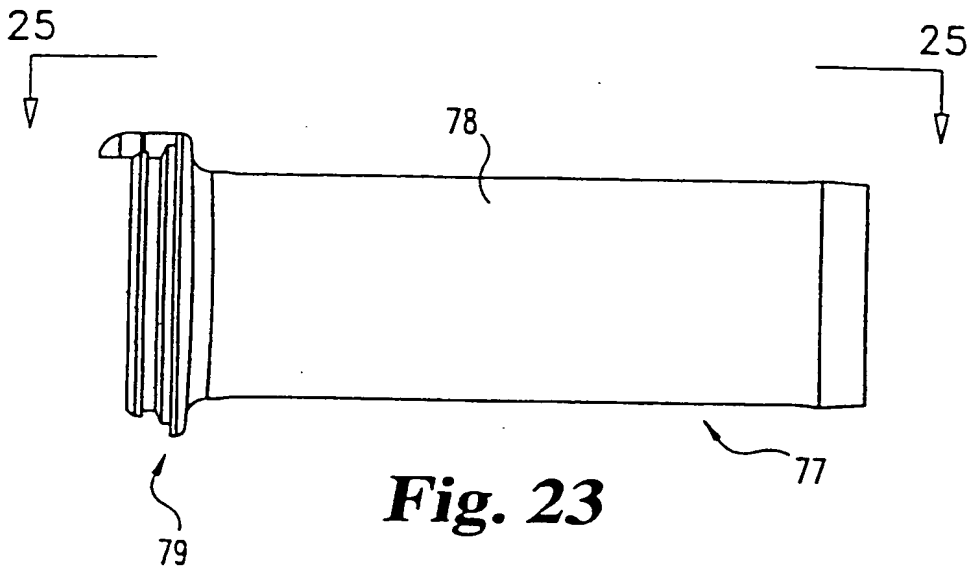
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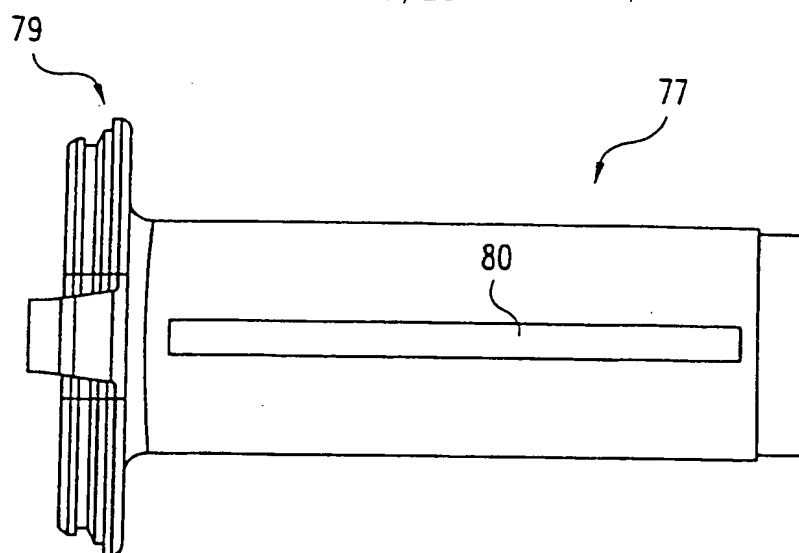
**Fig. 21**



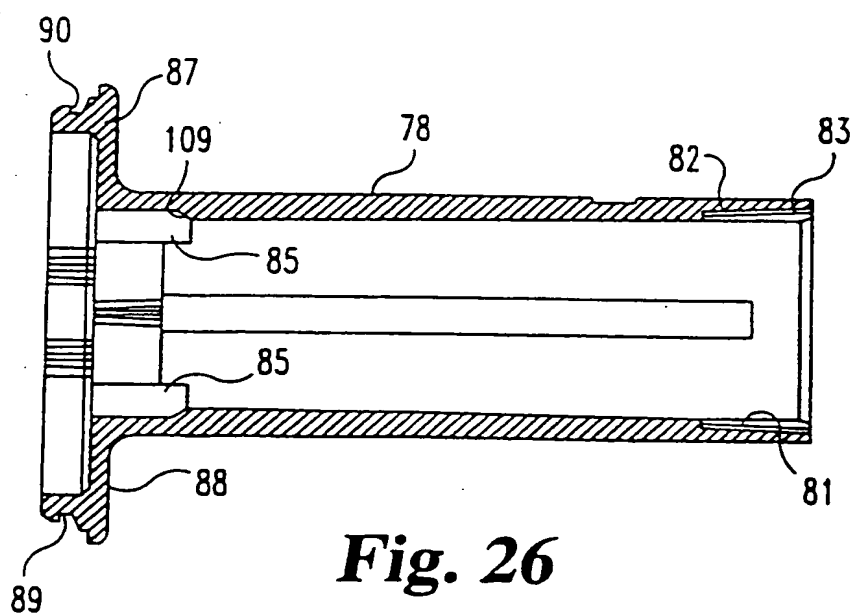
**Fig. 22**



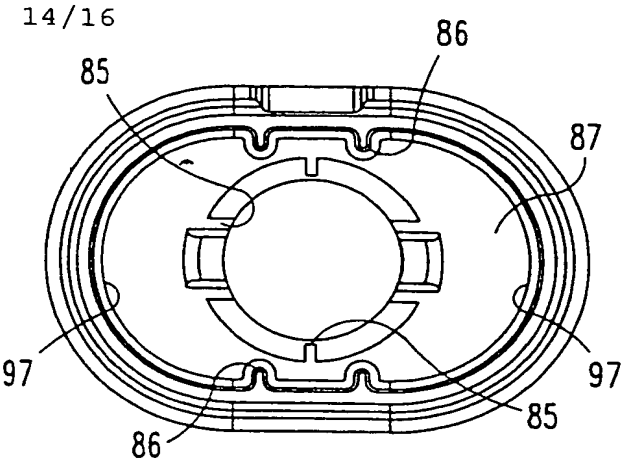
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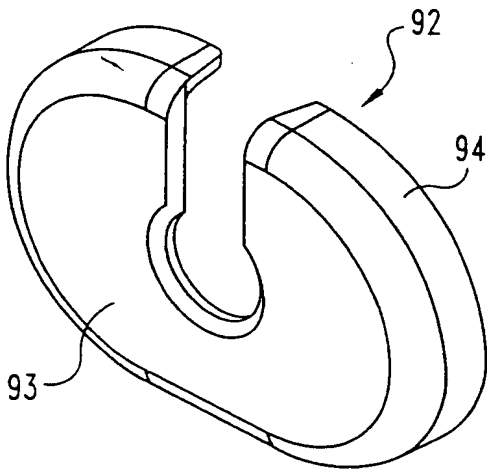
**Fig. 25**



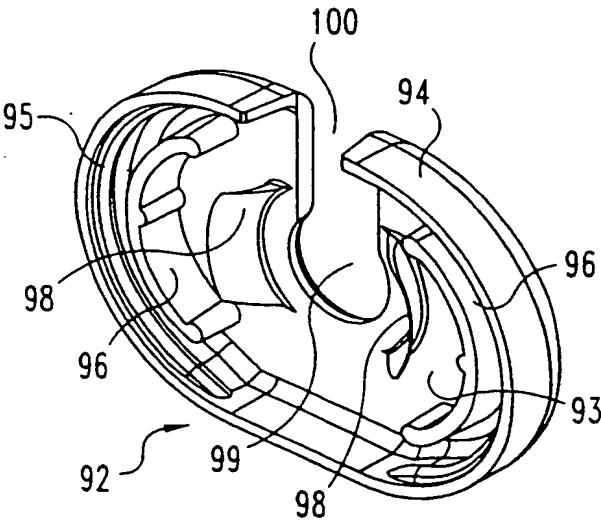
**Fig. 26**



**Fig. 27**



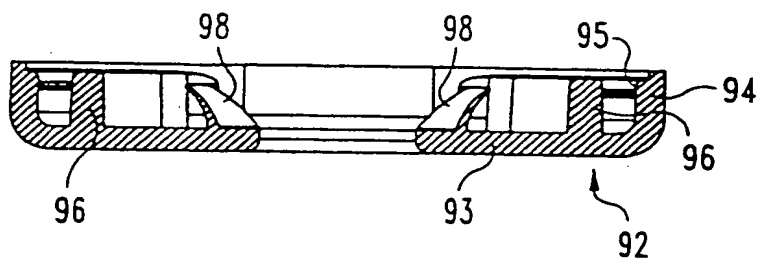
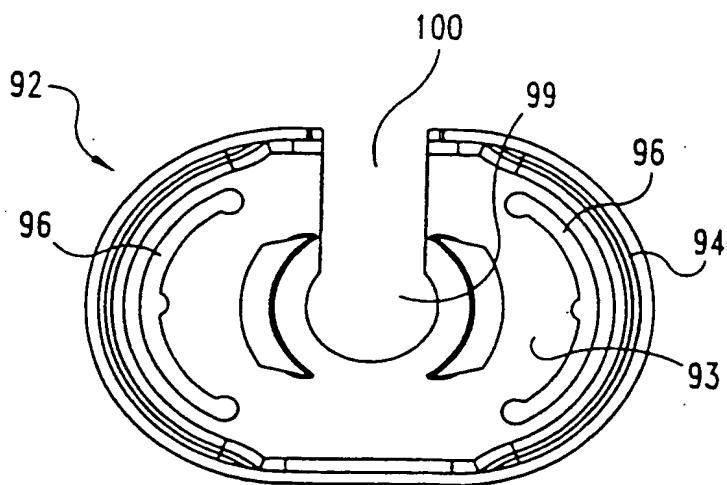
**Fig. 28**

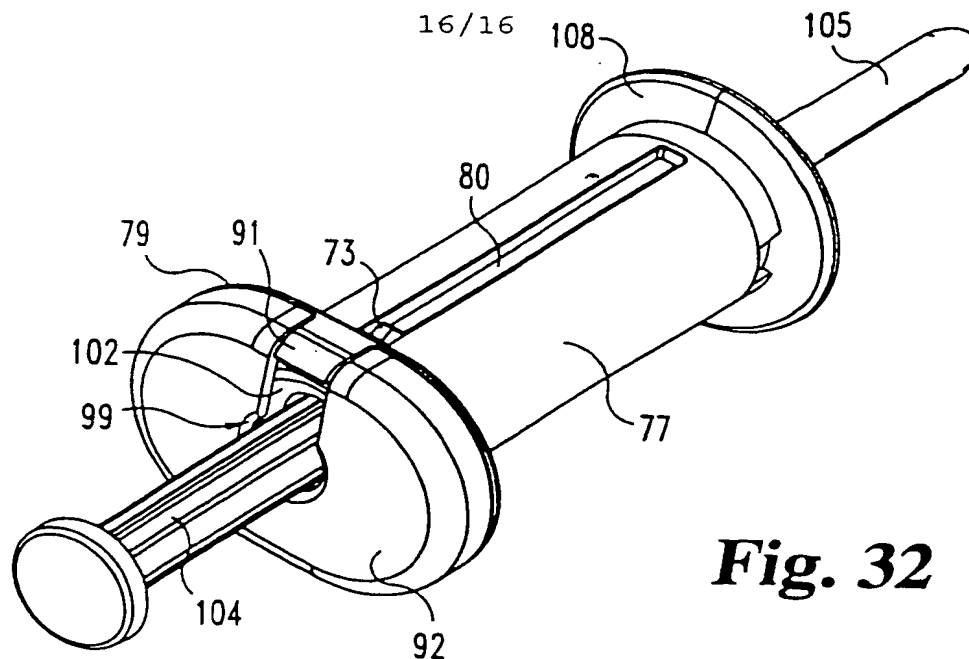


**Fig. 29**

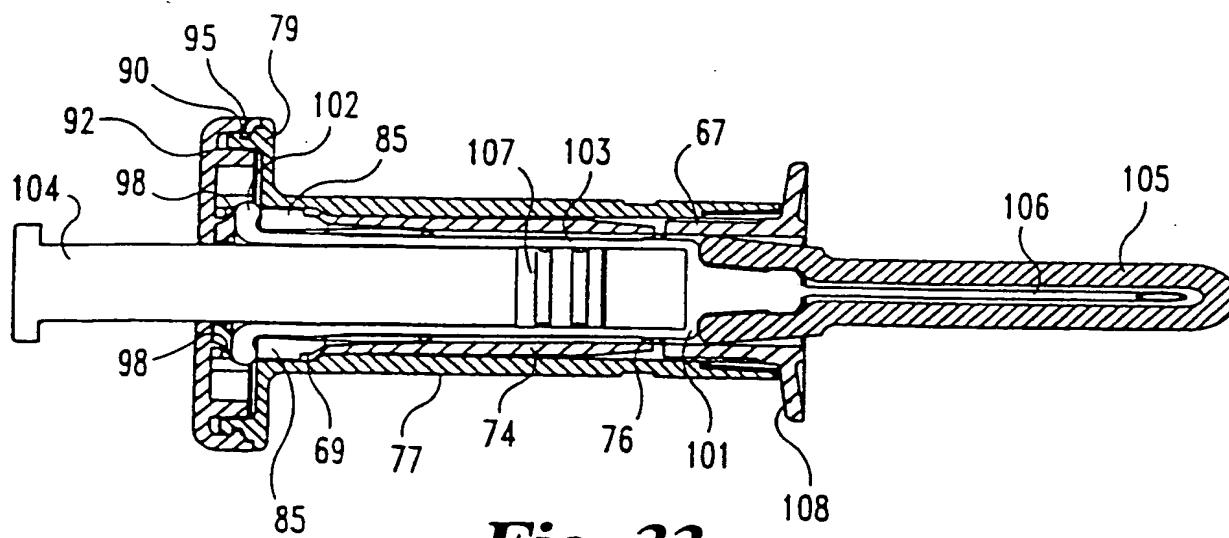


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**Fig. 30****Fig.31**



**Fig. 32**



**Fig. 33**

(19) World Intellectual Property Organization  
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Texarkana Drive, Indianapolis, IN 46231 (US). **MONSON, Rodney, Hal** [US/US]; 1008 South Park, Winthrop Harbor, IL 60096 (US). **YEAGER, Harold, Kenneth** [US/US]; 7913 Cove Trace, Indianapolis, IN 46256 (US).

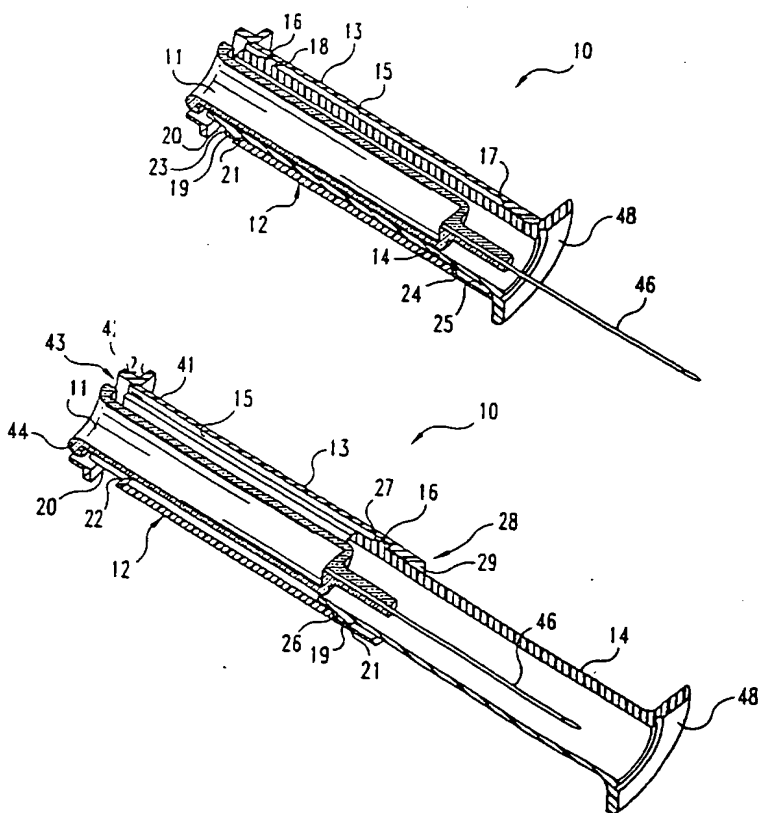
(74) Agents: **PREIN, Edward, J. et al.**; Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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[Continued on next page]

(54) Title: SAFETY DEVICE FOR A SYRINGE



(57) Abstract: A syringe safety device comprises telescoping inner and outer members. The members include complementary projections and recesses to limit the full extension of the inner member and to lock the inner member in place once it has been fully extended. The inner member includes a ring at the distal end which extends radially outward of the outer member and is pushed against to deploy the inner member. The outer member is secured to the proximal flange of a syringe received within the safety device. A clip or cover is attached to the outer member and secures the outer member to the syringe flange.

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IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report:  
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— with international search report

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/10808

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61M5/32 A61M5/50

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 29107 A (RADIOMETER MEDICAL AS ; LUND PER WILLIAM (DK); PETERSEN KNUD ROBERT) 26 September 1996 (1996-09-26) page 7, line 26 - page 8, line 5 page 9, line 10 - line 12 page 10, line 25 - line 27 figures	1
A	---	2, 3, 7, 27, 35
X	US 5 417 660 A (MARTIN ROBIN P) 23 May 1995 (1995-05-23) column 3, line 31 - line 54 abstract; figures	1
A	---	2-4, 27, 35
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Date of the actual completion of the international search

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	---	27, 35
A	US 5 891 092 A (CASTELLANO THOMAS P) 6 April 1999 (1999-04-06) column 7, line 26 - line 35; figures 4-6	1, 3, 27, 35
A	---	
A	US 5 921 964 A (MARTIN ROBIN) 13 July 1999 (1999-07-13) column 3, line 53 - column 4, line 7 figures 1-4 -----	1, 3, 4, 27, 35

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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